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EXAMINER	
HOWARD, ZACHARY C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,283	CHATTERJEE ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,17,29,37 and 38* is/are pending in the application.

4a) Of the above claim(s) *7,9-11,17,29,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☒ Claim(s) *1-11,17,29,37 and 38* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

Claims 1-11, 17, 29, 37 and 38 are pending in the instant application.

Election/Restrictions

Applicants' election without traverse of Group I, claims 1-11, in the reply filed on 2/26/09 is acknowledged.

Claims 17, 29, 37 and 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the 2/26/09 reply.

Three elections of species were also required in the Office Action mailed 2/10/09.

(1) Applicants' election of female as the species of patient sex is acknowledged. Applicants state that claims 1-4 and 6-11 read on this species. However, in the pending claims (11/19/05), claim 5 recites "[t]he method of claim 1, wherein the subject is female". Thus, claim 5 also reads on the elected species.

(2) Applicants' election of wherein the patient has been previously diagnosed with atherosclerosis as the species of patient history is acknowledged. Applicants state that claims 1-5 and 7-11 read on this species. However, in the pending claims (11/19/05), claim 6 recites "[t]he method of claim 1 wherein the subject has been previously diagnosed with atherosclerosis" and claim 7 recites "[t]he method of claim 1 wherein the subject has not been previously diagnosed with atherosclerosis". Thus, claim 6 and not claim 7 reads on the elected species.

(3) Applicants' election of non-infant as the species of patient age is acknowledged. Applicants state that claims 1-8 read on this species. The Examiner agrees.

Claims 7 and 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 1-6 and 8 are under consideration, as they read on the elected species.

Drawings

The drawings are objected to because:

(1) The Brief Description of Figure 7 on page 8 of the specification indicates that Figure 7 contains two parts (7A and 7B). However, Figure 7 itself does not include labels indicating these two parts. Figure 7 should be corrected to show parts A and B.

(2) Figure 13 is contains two labels: "Fig. 13" and "Figure 3." The "Figure 3" label is erroneous and should be deleted.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

(1) The title of the invention ("APOLIPOPROTEIN C-1 INDUCED APOPTOSIS") is not descriptive of the elected invention, which is directed to a method of determining risk of atherosclerosis-associated plaque rupture or myocardial infarction based on measuring the level of Apo-C1 in a sample from a subject. A new title is required that is clearly indicative of the invention to which the claims are directed.

(2) A corrected priority statement of the instant application’s parent provisional and nonprovisional applications should be included in the first sentence of the specification or application data sheet. Specifically, the priority statement should

indicate that the application is a 371 of PCT/US04/16419. The ADS filed 11/30/06 incorrectly indicates that the instant application is a Continuation of PCT/US04/16419.

(3) The description of Figure 9 begins "Figures 9A-9O depict…", whereas Figure 9 has parts A-P. The description does subsequently refer to Figure 9P (line 6 on pg 9), but for clarity the Brief Description of Figure 9 should start "Figures 9A-9P depict..."

(4) The Brief Description of Figure 12 (pg 12) does not contain a reference to each of parts A-D shown in the Figure. See 37 CFR § 1.74, which states “When there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures and to the different parts by use of reference letters or numerals (preferably the latter)” and MPEP 601.01(g) which states “if the drawings show Figures 1A, 1B, and 1C and the brief description of the drawings refers only to Figure 1, this is an error in the specification which must be corrected.”

Appropriate correction is required.

Application Data Sheet

An ADS was filed on 11/30/06 that includes incorrect "Domestic Priority Information". Specifically, the ADS incorrectly indicates that the instant application is a Continuation of PCT/US04/16419, rather than a 371 of PCT/US04/16419. The case was originally submitted under 35 U.S.C. 371 on 11/19/05 and was accepted under 35 U.S.C. 371 and 37 CFR 1.495 as indicated in the Notice mailed on 5/3/07.

Claim Objections

Claim 1 is objected to because of the following informalities:

In claim 1, the first usage of the abbreviation ApoCI should be accompanied by the full name of the protein as disclosed in the specification (see pg 2, line 6); e.g., claim 1, line 3 could be amended to recite: "...ApoCI (Apolipoprotein C-I) protein..."

In claim 1, line 7, after the term “protein”, the phrase “in the biological sample” should be added.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite for the following reasons. Claim 2 depends from claim 1 and recites "wherein the ApoCI protein is associated with elevated large HDL levels". It is unclear how "the ApoCI protein" (which is a tangible molecule; i.e., a protein) can be associated with "elevated large HDL levels" (which is in an intangible measurement; i.e., a quantity). Two tangible molecules can be associated (i.e., physical interacting); e.g., the ApoCI protein could bind to large HDL; or two intangible measurements can be associated (i.e., correlated); e.g., an increased level of ApoCI could be correlated with elevated levels of large HDL. For purposes of prosecution the claim will be interpreted to encompass either possibility. It is noted that if it is intended that "an increased level of the ApoCI protein" (as recited in line 7 of claim 1) is associated with "elevated large HDL levels", then the recitation of "the ApoCI protein" in claim 2 lacks sufficient antecedent basis.

Claim 3 is rejected for depending from an indefinite claim (claim 2).

Claim 4 recites the limitation “the sample” in line 2. There is insufficient antecedent basis for this limitation in the claim. Specifically, the antecedent basis of this recitation is unclear. The method steps of parent claim 1 include two different samples: the subject sample and the control sample. It is unclear which is being referred to in claim 4. For purposes of prosecution, this claim is interpreted broadly to encompass either possibility.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bjorkegren et al (2000. Circulation. 101: 227-230; reference CB on the 11/19/05 IDS).

Bjorkegren et al teach the measurement of the level of the ApoCI protein in plasma samples from 14 patients with coronary artery disease (CAD) and 14 control subjects without CAD. Bjorkegren et al found that "CAD patients manifested a postprandial accumulation of large, apo C-I-rich VLDLs, and their small VLDL remnants were enriched with apo C-I and cholesterol" (pg 229). The 14 CAD patients examined by Bjorkegren et al were all "myocardial infarction survivors" (pg 227). Myocardial infarction survivors inherently have some degree of "risk for developing atherosclerosis-associated plaque rupture" and "myocardial infarction". For evidence of this inherency, Flapan et al teach, "almost half of all survivors of acute myocardial infarctions died or suffered a further ischaemic event within three years" (pg 1129 of Flapan et al, 1994. BMJ. 309: 1129-1134; cited here solely to support inherency).

Thus, Bjorkegren et al teach a method that comprises step (a) of claim 1 (e.g., measuring the level of ApoCI protein in a biological (plasma) sample from a subject) and step (b) of claim 1 (e.g., comparing the level of ApoCI protein in said sample to the level from a control subject). Furthermore, Bjorkegren et al teach that the increased level of ApoCI protein is associated with patients with coronary artery disease but is not associated with control patients. Thus, the increased level of ApoCI protein indicates that the patient has coronary artery disease, and thus is at risk for developing

atherosclerosis-associated plaque rupture or myocardial infarction. Therefore, the teachings of Bjorkegren et al anticipate claim 1.

Claim 4 depends from claim 1 and recites "wherein the level of LDL in the sample is normal". As set forth in the section titled "Claim Rejections - 35 U.S.C. 112, 2nd Paragraph", the antecedent basis of "the sample" is unclear because it could refer to the subject sample or the control sample, and for the purposes of prosecution the claim has been interpreted broadly to refer to either sample. In the teachings of Bjorkegren et al, both the "subject" (patient) samples and the control samples had normal LDL levels (Table 1; CAD patient LDL is 3.36±0.53 and control LDL is 3.49±0.62).

Claim 6 depends from claim 1 and limits the method to one "wherein the subject has been previously diagnosed with atherosclerosis". As described above, the patients of the Bjorkegren et al are first described as having coronary artery disease, which is a form of atherosclerosis. Thus, the teachings of Bjorkegren et al described above also anticipate instant claim 6.

Claim 8 depends from claim 1 and limits the method to one "wherein the biological sample is selected from blood, serum and plasma". As described above, the samples used by Bjorkegren et al are plasma samples. Thus, the teachings of Bjorkegren et al described above also anticipate instant claim 8.

Claims 1-3 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Conde-Knape et al (2002. Journal of Lipid Research 43: 2136-2145; first published on 9/16/02 in JLR Papers in Press as stated at the bottom of the left column on pg 2136).

The "subject" of claim 1 broadly encompasses mice. Conde-Knape et al teach a transgenic apoE-null/C-I mouse (E_0CI) created by crossing a "moderately overexpressing human apoC-I transgenic" and an "apoE-null mouse" ($ApoE_0$)(Abstract). Conde-Knape et al teach that in these mice "HDL lipids were not significantly altered but HDL were apoC-I enriched..." (Abstract) and that "[h]uman apoC-I concentrations were determined in plasma and lipoproteins" (pg 2137; the lipoproteins were purified from the plasma as stated in the last paragraph of pg 2137). Conde-Knape et al further teach that said mice have "significantly more atherosclerosis" than control mice (pg 2142, right

column) when fed a "standard mouse chow diet" (pg 2137, right column). An apoE background mouse determined to have "significantly more atherosclerosis" is inherently one that is risk for developing atherosclerosis-associated plaque rupture. Mezdour et al (1997) teach that "mice completely lacking apoE develop atherosclerosis on a regular chow diet" (pg 13570 of Mezdour et al, 1997. Journal of Biological Chemistry. 272(21): 13570-13575; cited here solely to support inherency). Rosenfeld et al (2002) teach "high frequencies of intra-plaque hemorrhage in the innominate/brachiocephalic arteries of older, chow-fed, hyperlipidemic, apolipoprotein E-deficient mice" (see Abstract of Rosenfeld et al. 2002. Curr Atheroscler Rep. 4(3): 238-242).

Thus, Conde-Knape et al teach a method that comprises step (a) of claim 1 (e.g., measuring the level of ApoCI protein in a biological (plasma) sample from a mouse subject) and step (b) of claim 1 (e.g., comparing the level of ApoCI protein in said sample to the level from a control subject). Furthermore, Conde-Knape et al teach that these mice have increased atherosclerosis as compared to the controls. Thus, the increased level of ApoCI in the mice is associated with atherosclerosis, and thus indicates that the mouse is at risk for developing atherosclerosis-associated plaque rupture or myocardial infarction. Therefore, the teachings of Conde-Knape et al anticipate claim 1.

Claim 2 depends from claim 1 and recites "wherein the ApoCI protein is associated with elevated large HDL levels". This claim is indefinite for the reasons set forth in the section titled "Claim Rejections - 35 USC § 112, 2nd paragraph" but has been interpreted broadly to encompass increased levels of ApoCI protein that are associated with elevated large HDL levels. Conde-Knape et al further teach that the HDL from the mice described above (for claim 1) had "significantly higher core constituent ... to surface constituent" which is indicative of "larger particles" (pg 2139, left column). Thus, in these mice, the increased levels of ApoCI protein are associated with increased levels of larger HDL. Thus, the teachings of Conde-Knape et al also anticipate claim 2.

Claim 3 depends from claim 2 and recites "wherein the elevated large HDL is ApoCI-enriched". Claim 3 has been broadly interpreted in the same manner as claim 2 described above. As described above for claim 1, the mice had HDL that was ApoCI-

enriched. As described above for claim 2, the mice had increased levels of larger HDL particles. Therefore, in the human ApoCI-transgenic mice the elevated large HDL is ApoCI-enriched, and the teachings of Conde-Knape also anticipate claim 3.

Claim 8 depends from claim 1 and limits the method to one "wherein the biological sample is selected from blood, serum and plasma". As described above, the samples used by Conde-Knape et al are plasma samples. Thus, the teachings of Conde-Knape et al described above also anticipate instant claim 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bjorkegren et al (2000. Circulation. 101: 227-230; reference CB on the 11/19/05 IDS), as applied to claim 1 above, and further in view of McNamara et al (2001. Atherosclerosis. 154: 229-236).

Claim 5 depends from claim 1 and limits the method to a subject that is female.

The teachings of Bjorkegren et al are summarized above. Bjorkegren et al further teach that "[e]xaggerated postprandial triglyceridemia has been reported to be common

in humans with coronary artery disease (CAD). A significant fraction of the postprandial triglycerides are carried on intestinally derived cholymicrons. However, most of the triglyceride-rich lipoproteins (TRLs) that accumulate in the plasma after a meal are actually VLDLs" (pg 227).

Bjorkegren et al do not teach subjects that are female.

McNamara et al teach that "[t]he relationship between CVD and triglycerides is much stronger in women than in men in most of the studies" (pg 230).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute women for men in the method taught by Bjorkegren. The person of ordinary skill in the art would be motivated to do so because McNamara et al teach that the relationship between CVD and triglycerides is stronger in women than in men. A person of ordinary skill in the art would have a reasonable expectation of success because substituting women for men would simply require a simple substitution of one patient type for another; i.e., practicing the method as taught by Bjorkegren et al with female subjects and controls instead of male subjects and controls.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conde-Knape et al (2002. Journal of Lipid Research 43: 2136-2145; first published on 9/16/02 in JLR Papers in Press as stated at the bottom of the left column on pg 2136) as applied to claim 1 above, and further in view of additional teachings of Conde-Knape.

The teachings of Conde-Knape et al that anticipate claim 1 are described above. Conde-Knape does not teach a method of claim 1 wherein subject that is female (as recited in claim 5), or that has been previously diagnosed with atherosclerosis (as recited in claim 6).

Conde-Knape et al further teach that "E_0CI males had a 14-fold increase in TG compared to apoE_0 males, with a doubling of cholesterol, while E_0CI females had a 3-fold increase in TG compared to apoE_0 females, again with cholesterol levels that almost doubled (pg 2138). Conde-Knape et al further teach that the atherosclerosis studies of E_0CI mice, which showed they had significantly more atherosclerosis than the control (apoE_0) mice, were conducted using female mice (pg 2138, right column).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute female mice for male mice in the method taught by Conde-Knape et al. The person of ordinary skill in the art would be motivated to measure the level of increased ApoCI in the plasma HDL of female mice to compare with that of the male mice. A person of ordinary skill in the art would have had a reasonable expectation of success because (1) the female mice also had elevated triglycerides and cholesterol and (2) the female mice with these characteristics were also shown to have increased atherosclerosis. In view of the teachings of Conde-Knape et al, the female E_0CI mice have significantly increased atherosclerosis; therefore, the a female E_0CI mice subject would also constitute a "subject that has been previously diagnosed with atherosclerosis", as recited in claim 6.

Claim Rejections - 35 USC § 102/103

Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bjorkegren et al (2000. Circulation. 101: 227-230; reference CB on the 11/19/05 IDS).

Claim 2 depends from claim 1 and recites "wherein the ApoCI protein is associated with elevated large HDL levels". This claim is indefinite for the reasons set forth in the section titled "Claim Rejections - 35 USC § 112, 2nd paragraph" but has been interpreted broadly to encompass increased levels of ApoCI protein that are associated with elevated large HDL levels.

Claims 2 and 3 do not require that the practitioner of the claimed method actually measures the level of large HDL; instead the claim only requires that the quantity of "large HDL" in the subject is "elevated". Such encompasses the method of claim 1 wherein the patient in which ApoCI protein is measured also inherently has elevated levels of large HDL.

As described above, Bjorkegren et al teach a method that anticipates claim 1. Bjorkegren et al do not measure whether or not the subjects had "elevated large HDL levels" as recited in claim 2, or whether "the elevated large HDL is ApoCI-enriched" as recited in claim 3. As taught by the instant specification, "large HDL" is a specific

category HDL, for example with a "mean diameter of 11.6 nm" (¶ 214 of the published application).

The examiner is unable to determine whether the subjects used in the prior art (Bjorkegren et al) inherently also have "elevated large HDL levels" as recited in claim 2, and if so, whether said "elevated large HDL is ApoCI-enriched". If said subjects do inherently have "elevated large HDL levels", said characteristic is inherently associated with the "increased level of ApoCI protein" found in said subjects, and the teachings of Bjorkegren et al meets the limitations of claim 2. If said subjects inherently have ApoCI-enriched elevated large HDL, then the teachings of Bjorkegren et al also meet the limitations of claim 3.

With these conditions, where a method seems to be identical except that the prior art is silent to the characteristic or property claimed, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977).

Art of Note

The following articles, patents, and published patent applications were found by the Examiner during the art search and while not relied upon for a rejection are considered pertinent to the instant application:

(1) Kolmakova et al (2004. Arterioscler Thromb Vasc Biol. 24: 264-269) show that that the ApoCI protein, as well as HDL particles enriched with ApoCI, stimulate apoptosis in cultured human aortic smooth muscle cells (ASMC). Kolmakova et al teach that "ASMC play a critical role in preventing the complications of atherosclerosis as part of the fibrous cap that sequesters the lipid core and prevents plaque rupture" (pg 265) and ApoCI promoting apoptosis of ASMC "may contribute to an unstable plaque that is more likely to rupture leading to thrombosis, myocardial infarction, and death" (pg 265). These teachings support Examples 1-7 of the instant specification.

(2) Steen et al (2007. Atherosclerosis. 191: 82-89). This publication supports Examples 8 and 9 of the instant specification, which describe a rabbit model of

atherosclerotic stages that was fed high fat and cholesterol and exhibited "plaque having large oil droplets" and "pronounced immuno-histochemical staining of the aortic intima with the ApoCI antibody" as compared to the control rabbits (pg 60).

(3) Kwitterovich et al (2005. JAMA. 293: 1891-1899). This publication supports Examples 10-15 of the instant specification, which describe a study of cholesterol, triglycerides, LDL and HDL cholesterol, Lp(a) lipoprotein, and various apolipoproteins including CI in the cord blood from 163 infants, including 23 that were small-for-gestational age (SGA). The study found that "ApoCI, ordinarily a minor component of HDL, was the second most prevalent apolipoprotein (37.6%)" (pg 64). The infants were placed in groups based on the amount of ApoCI-enriched HDL detected. Kwitterovich et al teaches that "[i]nfants with elevated apo C-I-enriched HDL (group 3) were further unique in that they had notably lower birth weights and younger gestational ages and significantly different plasma levels of lipids, lipoproteins, apolipoproteins, and lipoprotein subclasses and lipoprotein size than infants with undetectable (group 0), possible (group 1) or probable (group 2) apo C-I-enriched HDL" (pg 1896-1897). Kwitterovich et al further teach that "[l]ow birth weight is associated with cardiovascular risk factors and death in adulthood".

(4) van der Ham et al (2009. Atherosclerosis. 203: 355-357). This publication teaches that "Apolipoprotein CI levels are associated with atherosclerosis in men with the metabolic syndrome and systemic inflammation" (pg 355) and that "in an early phase of atherogenesis … high [plasma] ApoCI and systemic inflammation were associated with increased MVT [maximum vessel wall thickness] at the level of the carotid bulb" (pg 356).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E Bunner/
Primary Examiner, Art Unit 1647